I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on By:

<u>PATENT</u>

Attorney Docket No.: 02307O-138122US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GERMAN, Michael S., et al.

Application No.: Filed Herewith

Filed: December 11, 2003

For: DELIVERY OF POLYPEPTIDES

BY SECRETORY GLAND

EXPRESSION

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on attached forms PTO/SB/08A, PTO/SB/08B and PTO-1449 are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/550,302, filed April 14, 2000, (Attorney Docket No. 02307O-138120US).

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

<u>PATENT</u>

Page 2

Applicant believes that <u>no fee is required</u> for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Dated: December 11, 2003

Nicholas V. Sherbina

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NVS:mmm 60099373 v1

Substitu	ite for form 1449A/P1	го			Complet if Known
				Application Number	Filed Herewith
INFO	ORMATION	I DIS	SCLOSURE	Filing Date	December 11, 2002
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	German, Michael S.
				Art Unit	Unassigned
	(use as many sh	eets a	s necessary)	Examiner Name	Unassigned
Sheet	1	of	3	Attorney Docket Number	02307O-138122US

	U.S. PATENT DOCUMENTS+								
		Document Number							
Examiner Initials*	Cite No. ¹	Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
	AA	US-5,166,320	11/24/1992	Wu, et al.					
	AB	US-5,670,347	09/23/1997	Gopal					
	AC	US-5,766,899	06/16/1998	Kuo, et al.					
	AD	US-5,792,751	08/11/1998	Ledley, et al.					
	AE	US-5,827,703	10/27/1998	Debs, et al.					
	AF	US-5,858,351	01/12/1999	Podsakoff, et al.					
	AG	US-6,083,905	07/04/2000	Voorberg, et al.					
	ΑĤ	US-6,093,392	07/25/2000	High, et al.					
	Al	US-6,177,554	01/23/2001	Woo, et al.					
	AJ	US-6,265,387	07/24/2001	Wolff, et al.					

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Country Code ³	oreign Patent Document Number ⁴	Kind Code ⁵ (<i>il</i> known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T⁵	
	AK	PCT	WO 91/06309 A1		05/16/1991	Univ. Vanderbilt			
	AL	PCT	WO 93/19660 A1		10/14/1993	Baylor College Medicine			
	AM	PCT	WO 94/29471 A1		12/22/1994	Genetic Therapy Inc.			
	AN	PCT	WO 95/02698		01/26/1995	Life Technologies Inc.			
	AO	PCT	WO 96/30050		10/03/1996	Univ. California			

Examiner Signature	Date Considered	

Substitute for form 1449B/PTO Complete if Known Application Number Filed Herewith **INFORMATION DISCLOSURE** Filing Date December 11, 2002 STATEMENT BY APPLICANT First Named Inventor German, Michael S. Art Unit To be assigned (use as many sheets as necessary) Examiner Name To be assigned Sheet Attorney Docket Number 02307O-138122US

		NON PATENT LITERATURE DOCUMENTS	-,				
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т				
	AP	ABEMDROTH, et al., AN96126219, (1996).					
	AQ	ANDERSON, et al., "Human gene therapy," Nature, Vol. 392, pp. 25-30, (1998).					
-	AR	Biotechnology, Vol. 10, pp. 132-136, (1992).					
	AS	BRUINSMA, et al., "Towards a new gene transfer system: Shock wave-mediated DNA transfer," pp. 102-103, (1994).					
	AT	GUMUCIO, D. L., et al., "Concerted Evolution of Human Amylase Genes," Mol. Cell. Biol., Vol. 8, No. 3, pp. 1197-1205, (1988).					
	AU	HATZOGLOU, M., et al., "Hepatic Gene Transfer in Animals Using Retroviruses Containing the Promoter from the Gene for Phosphoenolpyruvate Carboxykinase," <i>J. Biol. Chem.</i> , Vol. 265, pp.17285-17293, (October 1990).					
	AV	HICKMAN, et al., "Gene expression following direct injection of DNA into liver," pp. 1477-1483, (1994).					
	AW	HICKMAN, et al., "Therapeutic response produced by direct," p. 241, (1994).					
	AX	MELLITUS, Journal of Endocrinology, Vol. 143, pp. 339-343, (1994).					
	AY	OSBORN, L., et al., "Insulin Response of a Hybrid Amylase/CAT Gene in Transgenic Mice," J. Biol. Chem., Vol. 263, No. 32, pp. 16519-16522, (November 1988).					
	AZ	PONDER, AN2000103902, (1999).					
	ВА	SCHMID, R., et al., "Liposome Mediated in vivo Transfer Into Different Tissues of the Gastrointestinal Tract," Zeitschrift fuer Gastroenterologie, Vol. 32, No. 12, pp. 665-670, (1994).					
	ВВ	SOSA-PINEDA, et al., "The pax4 gene is essential for differentiation of insulin-producing beta cells in the mammalian pancreas," <i>Nature,</i> Vol. 386, pp. 399-402, (1997).					
	вс	TRIPATHY, S.K., et al., "Stable delivery of physiologic levels of recombinant erythropoietin					
	VALERA, et al., "Regulated Expression of Human Insulin in the Liver of Transgenic Mice Corrects Diabetic Alterations," <i>Research Communications</i> , US, FED. OF AMERICA SOC. FOR EXPERIMENTAL BIOLOGY, BETHESDA, MD, (April 1994), Vol. 8., No. 8., pg. 440, paragraph 4, pg. 441, paragraph 2.						

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Considered

Signature

Substitute	for form 1449B/PT	0		Complete if Known			
INITO	DALATION	DIC	OL OCUPE	Application Number	Filed Herewith		
			CLOSURE	Filing Date	December 11, 2002		
STAT	EMENT B	YA	PPLICANT	First Named Inventor	German, Michael S.		
				Art Unit	To be assigned		
((use as many sheets as necessary)			Examiner Name	To be assigned		
Sheet	3	of	3	Attomey Docket Number	02307O-138122US		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	BE	VERMA, et al., "Gene therapy-promises, problems and prospects," <i>Nature</i> , Vol. 389, pp. 239-242, (1997).				
	BF	YAMADA, et al., "In vivo identification of a negative regulatory element in the mouse rennin gene using direct gene transfer," J. Clin. Invest., Vol. 96, pp. 1230-1237, (1995).				

Examiner		Date	
Signature	1	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Form PTO-1449 (Modified)

(Use several sheets if necessary)

ATTY. DOCKET NO.	SERIAL NO.
02307O-138122US	Filed Herewith
Applicant GERMAN, Michael S.	
FILING DATE	GROUP
December 11, 2003	To be assigned

U.S. PATENT DOCUMENTS

Examiner		Document Number	Date	Name	Class		
Initial			. Date		· Class	Subclass	Filing Date -
IIIIciai							If Appropriate
ļ	AA	4,394,443	07/19/83	Weissman, et al.	435	6 .	12/18/80
	AB	4,683,195	·· 07/28/87	Mollis, et al.	435	6	02/07/86
·	AC	4,683,202	07/28/87	Mollis	435	91	10/25/85
	AD	4,703,008	10/27/87	Lin	C12N	5/00	11/30/84
	AE	4,861,719	08/29/89	Miller, et al.	435	236	04/25/86
	AF	5,139,941	08/18/92	Muzyczka, et al.	435	172.3	10/25/91
	AG	5,219,740	06/15/93	Miller, et al.	435	69.6	02/13/87
	AH	5,240,846	08/31/93	Collins, et al.	435	240.1	09/18/90
	Al	5,292,662	03/08/94	Sandmeyer	435	320.1	06/08/92
	AJ	5,328,470	07/12/94	Nabel, et al.	604	101	07/26/91
	AK	5,356,806	10/18/94	Harris, et al.	435	240.2	04/13/92
	AL	5,399,346	03/21/95	Anderson, et al.	424	93.21	03/30/94
	АМ	5,589,466	12/31/96	Felgner, et al.	A61K	48/00	01/26/95
	AN	6,004,944	12/21/99	Rothman, et al.	. A61K	48/00	10/02/97

FOREIGN PATENT DOCUMENTS

	Document Number Date Country		Class	Subclass	Trans	lation	
			•	<u> </u>		Yes	No
AO	WO 94/26915	11/24/94	PCT	C12N	15/86	•	XX
AP	WO 99/17610	11/15/99	PCT	C12N	13/00		XX

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	1	Amsterdam, et al., "Studies on Dispersed Pancreatic Exorcine Cells," J. Cell. Biol., 63:1057-1073 (1974).
•	1	Avery, et al., "Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types," <i>J. Exp. Med.</i> , 174:137-158 (1994).
		Baum, "Advances in Salivary and Soft Tissue Management," JADA, 125:26S-30S (1994).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 (Modified)

ATTY. DOCKET NO. 02307O-138122US	SERIAL NO. Filed Herewith
Applicant: GERMAN, Michael S.	
FILING DATE December 11, 2003	GROUP To be assigned

· ·	
	OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
	g
A	Boshart, et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of
	Human Cytomegalovirus," Cell, 41:521-520 (1985).
AL	Brody, et al., "Adenovirus-Mediated In Vivo Gene Transfer," NY Acad. Sci., 716:90-101 (1994).
· AV	Cockell, et al., "Identification of a Cell-Specific DNA-Binding Activity that Interacts with a
	Transcriptional Activator of Genes Expressed in the Acinar Pancreas," Mol. Cell. Biol., 9:2464-
	2476 (1989).
AV	Coghlan, "Gene Dream Fades Away," New Scientist, (Nov. 1995):14-15.
AX	Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," Science,
	270:404-410 (1995).
AY	Elango, et al., "Molecular Cloning and Characterization of Six Genes, Determination of Gene Order
	and Intergenic Sequences and Leader Sequence of Mumps Virus," J. Gen. Virol., 69:2893-2900
·	(1988).
AZ	Felgner, et al., "Lipofection: A Highly Efficient, Lipid-Mediated DNA-Transfection Procedure," Proc.
<u> </u>	Nat'l. Acad. Sci. USA, 84:7413-7417 (1987).
ВА	Fynan, et al., "DNA Vaccines: Protective Immunizations by Parenteral, Mucosal, and Gene-Gun
	Inoculations," Proc. Nat'l. Acad. Sci. USA, 90:11478-11482 (1993).
BB	Gerrard, et al., "Towards Gene Therapy for Haemophelia B Using Primary Human Keratinocytes,"
	Nat. Genet., 3:180 (1993).
BC	Gitschier, et al., "Characterization of the Human Factor VIII Gene," Nature, 312:326-330 (1984).
BD	Gorman, et al., "The Rous Sarcoma Virus Long Terminal Repeat is a Strong Promoter when
	Introduced into a Variety of Eukaryotic Cells by DNA-Mediated Transfection," Proc. Nat'l. Acad.
	Sci. USA, 79:6777-6781 (1982).
BE	Grendell, et al., "Effect of Changes in Circulating Amylase Levels on Amylase Output in Bile," The
	American Physiological Socitey, G54-G59 (1982).
BF	Groot, et al., "The Human α-Amylase Multigene Family Consists of Haplotypes with Variable
	Numbers of Genes," <i>Genomics</i> , 5:29-42 (1989).
BG	Gunzberg, et al., "Virus vector design in gene therapy," Molecular Medicine Today 410-417
· .	(1995).
ВН	Hagenbuchle, et al., "Expression of Mausy Amy-2" Alpha-Amylase Genes is Regulated by Strong
	Pancreas-Specific Promoters," <i>J. Mol. Biol.</i> , 185:285-293 (1985).
BI	Hewitt, et al., "Human Gastric Intrinsic Factor: Characterization of cDNA and Genomic Clones and
	Localization to Human Chromosome 11," Genomics, 10:432-440 (1991).

EXAMINER	DATE CONSIDERED		
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Form PTO-1449 (Modified)

ATTY, DOCKET NO.	SERIAL NO.
023070-138122US	Filed Herewith
Applicant: GERMAN, Michael S.	
FILING DATE	GROUP
December 11, 2003	To be assigned

	OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
	The state of the s
TRI	longs at al. "A Salivan, Amulas Tarana, '- Fff'
	Jones, et al., "A Salivary Amylase Transgene is Efficiently Expressed in Liver but Not in Parotid
DV DV	Gland of Transgenic Mice," Nucleic Acid Res., 17(6):6613-6623 (1989).
D^	Korman, et al., "Expression of Human Class II Major Histocompatibility Complex Antigens Using
	Retrovirus Vectors," Proc. Nat'l. Acad. Sci. USA, 84:2150-2154 (1987).
BL	Kozarsky, et al., "Adenovirus-Mediated Correction of the Genetic Defect in Hepatocytes from
	Patients with Familial Hypercholesterolmia," Somat. Cell Mol. Genet., 19(5):449-458 (1993).
BM	Kwano, et al., "Complete Nucleotide Sequence of the Matrix Gene of Human Parainfluenza Typ 2
	Virus and Expression of the M Protein in Bacteria," Virol., 179:857-861 (1990).
. BN	Ledley, "Nonviral gene therapy: the promise of genes as pharmaceutical products," Human Gene
	Therapy, 6:1129-1144 (1995).
BO	Lowry, et al., "Protein Measurement with the Folin Phenol Reagent," J. Biol. Chem., 193:265-275
	(1951).
BP BP	Maeda, et al., "Adenovirus-Mediated Transfer of Human Lipase Complementary DNA to the
	Gallbladder," Gastroentreology, 106:1638-1644 (1994).
BQ	Marshall, et al., " Less Hype, Mor Biology Needed for Gene Therapy," Science, 270:1751 (1995).
	Marshall, "Gene Therapy's Growing Pains," Science, 269(5227):1050 (1995).
BS	Martial, et al., "Human Growth Hormone: Complementary DNA Cloning and Expression in
	Bacteria," <i>Biotechnology</i> , 24:293-298 (1992).
BT	Mastrangeli, et al., "Direct In Vivo Adenovirus-Mediated Gene Transfer to Salivary Glands," Am. J.
	Physiol., 266:(6, part 1):G1146-55 (1994).
BU	Mastrangelo, et al., "Gene Therapy for Human Cancer: An Essay for Clinicians," Seminars in
	Oncology, 23:4-21 (1996).
BV	Miller, et al., "Targeted Vectors for Gene Therapy," FASEB J., 9(2):190-199 (1995).
BW	Miyasaka, et al., "Endocrine Secretion of α-Amylase by the Process by the Pancreas," <i>American</i>
	Physiological Society, G170-G175 (1981).
BX	Morgan, et al., "Expression of an Exogenous Growth Hormone Gene by Transplantable Human
	Epidermal Cells," <i>Science</i> , 237:1476-1479 (1987).
BY	Morsy, et al., "Progress Toward Human Gene Therapy," JAMA, 270:2338-2345 (1993).
BZ	Mulligan, "The Basic Science of Gene Therapy," Science, 260:926-932 (1993).
CA	Newgard, et al., "Molecular Engineering of the Pancreatic β-Cell," J. Lab. Clin. Med., 122(4):356-
	363 (1993).
СВ	Orkin, et al., "Report and Recommendations of the Panel to Assess the NIH Investment in
	Research on Gene Therapy," December 7, 1995.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in not in conformance and not considered. Include copy of this form with	n conformance with MPEP 609; Draw line through citation if next communication to applicant.

INFORMATION DISCLOSURE CITATION Form PTO-1449 (Modified)

ATTY. DOCKET NO.	SERIAL NO.
02307O-138122US	Filed Herewith
Applicant: GERMAN, Michael S.	
FILING DATE	GROUP
December 11, 2003	To be assigned

		OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
	CC	Pittet, et al., "Mouse Alpha-Amylase Loci, Amy-2" and Amy-1", are Closely Linked," J. Mol. Biol
		182:359-365 (1985).
•	CD	Ramakrishna, et al., "Gene Therapy for Exorcrine Pancreatic Insufficiency," Gastroenterology,
·		106(6):1711-1713 (1994).
	CE	Robins, et al., "Retrotransposons sand the Evolution of Mammalian Gene Expression," Genetica
		86:191-201 (1992).
	CF	Rosenfeld, et al., "Adenovirus-Mediated Transfer of a Recombinant αl-Antitrypsin Gene to th
		Lung Epithelium In Vivo," Science, 252:431-434 (1991).
٠.	- CG	Rosenfeld, et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance
		Regulator Gene to the Airway Epithelium," Cell, 68:143-155 (1992).
	СН	Samara, et al., "Molecular Biology and Therapy of Disease," The American Journal of Surgery,
		165:720-727 (1993).
	CI	Samuelson, et al., "Expression of the Human Amylase Genes: Recent Origin of a Salivary Amyla
		Promoter from an Actin Pseudogene," Nucleic Acids Res., 16:8261-8276 (1988).
	C1	Schibler, et al., "Structural Arrangement of and Tissue-Specific Expression of the Two Murine
		Alpha-Amylase Loci Amy-1 and Amy-2," Oxf. Surv. Eukaryot. Genes, 3:210-234 (1986).
	СК	Sierra, et al., "Different Tissue-Specific Expression of the Amylase Gene Amy-I in Mice and Rate
		Mol. Cell. Biol., 6(11):4067-4076 (1986).
	CL	Stewart, et al., "Insulin Delivery by Somatic Cell Gene Therapy," J. Mol. Endocrinol., 11(3):335
		341 (1993).
	СМ	Stewart, et al., "Insulin-Releasing Pituitary Cells as a Model for Somatic Cell Gene Therapy," J.
		Mol. Endocrinol., 143:339-343 (1994).
	CN	Suggs, et al., "Use of Synthetic Oligonucleotides as Hybridization Probes: Isolation of Cloned
	<u> </u>	cDNA Sequences for Human β2-Microglobulin,"
	co	Takeuchi, et al., "In Vitro Transcription and Replication of the Mumps Virus Genome," Archiv.
		Virol., 128:177-183 (1993).
	СР	Tanabayashi, et al., "Expression of Mumps Virus Glycoproteins in Mammalian Cells from Cloned
		cDNA's: Both F and HN Proteins are Required for Cell Fusion," Viral., 187:801-804 (1992).
	ca	Tanabayashi, et al., "Identification of an Amino Acid that Defines the Fusogenicity of Mumps
		Virus," <i>J. Virol.</i> , 67 :2928-2931 (1993).
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	1	Human Salivary Amylase Gland," <i>Genes Dev.</i> , 6:1457-1465 (1992).

	·		
EXAMINER	DATE CONSIDERED		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if			
not in conformance and not considered. Include copy of this form with	n next communication to applicant.		

Form PTO-1449 (M diffied)

ATTY, DOCKET NO. 023070-138122US	SERIAL NO. Filed Herewith
Applicant: GERMAN, Michael S.	
FILING DATE	GROUP
December 11, 2003	To be assigned

		OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
	cs	Tomita, et al., "A Novel Type of Human α-Amylase Produced in Lung Carcinoid Tumor," Gene,
		76:11-18 (1989).
7	. CT	Towbin, et al., "Electrophoretic Transfer of Proteins from Polyacrylamide Gels to Nitrocellulose
	·	Sheets: Procedure and Some Applications," Proc. Nat'l. Acad. Sci. USA, 76:4350-4354 (1979)
	CU	Wolff, et al., "Direct Gene Transfer into Mouse Muscle In Vivo," Science, 247:1465-1468 (1990).
	CV	Wood, et al., "Expression of Active Human Factor VIII from Recombinant DNA Clones," <i>Nature</i> , 312:330-337 (1984).
	cw	Yang, et al., "In Vivo and In Vitro Gene Transfer to Mammalian Somatic Cells by Particle
		Bombardment," Proc. Nat'l. Acad. Sci. USA, 87:9568-9572 (1990).
	cx	Taniguchi, et al., "Constant delivery of proinsulin by encapsulation of transfected cells," J.
		Surgical Res., 70:41-45 (1997).
	CY	Adesanya, et al., "Immediate Inflammatory Responses to Adenovirus-Mediated Gene Transfer in
<u> </u>		Rat Salivary Glands," Human Gene Therapy, 7:1085-1093 (June 10, 1996).
	CZ	Barka, et al., "Retrovirus-Mediated Gene Transfer into Salivary Glands In Vivo, "Human Gene
		Therapy, 7:613-618 (March 20, 1996)
	DA	Buckel, et al., "Recombinant proteins for therapy," TiPS, 17:450 (1996).
		Curiel, et al., "Gene transfer to respiratory epithelial cells via the receptor-mediated endocytosis pathway," <i>Am. J. Respir. Cell. Mol. Biol.</i> , 6(3):247-252 (1992).
	DC	Friedmann, "Human gene therapyan immature genie, but certainly out of the bottle," <i>Nature Med.</i> , 2:144 (1996).
	DD	Geokas, et al., "Molecular forms of immunoreactive pancreatic elastase in canine pancreatic and
		peripheral blood," Am. J. Physiol., 238:238-246 (1980).
		Hahn, et al., "Phenotypic Correction of Dwarfism by Constitutive Expression of Growth Hormone,"
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		Isenman, et al., "Transport of α-Amylase Across the Basolateral Membrane of the Pancreatic
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	DG	Kagami, et al., "Evidence for the Systemic Delivery of a Transgene Product from Salivary Glands,"
		Human Gene Therapy, 7:2177-2184 (Nov. 10, 1996).

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in	n conformance with MPEP 609; Draw line through citation if
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Form PTO-1449 (Modified)

SERIAL NO. Filed Herewith
GROUP To be assigned

	•	OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
٠.		
	DH	Kolodka, et al., "Gene Therapy for Diabetes in Mellitus in Rats by Hepatic Expression of Insulin,"
		Proc. Nat'l. Acad. Sci. U.S.A ., 92:3293-3297 (April, 1995).
	DI	O'Connell, et al., "Facilitated DNA Transfer to Rat Submandibular Gland In Vivo and GRP-Ca Gen
		Regulation, " Am. J. Physiol., 268:G1074-G1078 (1995).
	DJ	O'Connell, et al., "Transfer of a Gene Encoding the Anticandidal Protein Histatin 3 to Salivary
	L	Glands," Human Gene Therapy., 7:2255-2261 (Dec. 1, 1996).
	DK	Papp, et al., Acta. Physiol. Acad. Sci. Hung., 56:4068-4072 (1997).
	DL	Raper, et al., "Adenovirus-Mediated In Vivo Gene Transfer and Expression in Normal Rat
		Pancreas," <i>Pancreas</i> , 12(4):401-410 (1996).
	DM	Saito, et al., "Concentration of pancreozymin as a determinant of the exocrine-endocrine partition
		of pancreatic enzymes.," Jpn. J. Physiol. 23:477-95 (1973).
	DN	Stewart, et al., "Insulin Delivery by Somatic Cell Gene Therapy," Journal of Molecular
·	Ŀ	Endocrinology, 11:335-341 (1993).
	DO	Goldfine, et al., "The Endocrine Secretion of Human Insulin and Growth Hormone by Exocrine
		Glands of the Gastrointestinal Tract," Nat. Biotechnol, (1997) Dec; 15(13):1378-82.
	<u> </u>	
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EXAMINER		DATE CONSIDERED				
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if						
not in conformance and not co	nsidered. Include copy of this form wit	h next communication to applicant.				